## REMARKS

Claims 1, 4, 42, 43, 45-49, and 59-67 are pending. Claims 1, 4, 42, 43, 45-49, and 59-67 stand rejected under 35 U.S.C. § 102. Applicants address this basis for rejection as follows.

Rejection under 35 U.S.C. § 102

Claims 1, 4, 42, 43, 45-49, and 59-67 stand rejected under 35 U.S.C. § 102(b) as anticipated by Vollmers et al. (Cancer 76:550-558, 1995; hereafter "Vollmers"), as evidenced by Hensel et al. (Cancer Research 59:5299-5306, 1999; hereafter "Hensel"). Applicants respectfully traverse this basis for rejection.

In asserting that Vollmers describes the purified glycoprotein encompassed by the claims, the Office states (page 4):

> The 23132 cell extract isolated in Vollmers is the same as Hensel's and inherently contains the same glycoprotein of about 82 kDa, see Vollmers page 552, Western Blots sections and Hensel, page 5300, first column, Purification ... section.

Applicants disagree with the Office's characterization of the Vollmers reference. The cell extract described in Vollmers is, in fact, not the same as the membrane extract described in Hensel where the 82 kD protein was detected.

Applicants direct the Office's attention to Vollmers, which, at page 552 in the "Western Blots" section (left column), states:

> The extracts were cleared of nuclei and cell debris by centrifugation at 12,000*g* for 5 minutes, diluted with Laemmli sampling buffer for SDS-gel electrophoresis, and heated to 95°C.

The extracts used in Vollmers are whole cell lysates cleared of nuclei and cell debris. In contrast, Hensel, at page 5300 in the "Purification of the SC-1 Receptor" section, states:

> For preparation of membrane proteins, harvested cells were resuspended in hypotonic buffer (20 mM HEPES, 3 mM KCl, 3 mM $MgCl_2$), incubated on ice (15 min), and sonicated (5 min), and nuclei were pelleted by centrifugation (10,000 x *g* for 10 min). The membranes were pelleted by centrifugation (100,000 x *g* for 30 min) and resuspended in membrane lysis buffer.

From this description, it is clear that, in Hensel, like in Vollmers, the whole cell lysates were cleared of nuclei by centrifugation. However, Hensel then pellets the membranes from the lysate

and resuspends the membrane fraction. It is in this purified membrane fraction that Hensel is able to detect the 82 kD protein.

Like Hensel, Applicants' specification also describes the use of membrane fractions to purify the 82 kD protein encompassed by the claims. The specification, in the section entitled "2.1 Purification of the SC-1 Receptor CD55" at page 28 of the English language translation, states (emphasis added):

> In Western-blot analysis of extracts from total cell lysates of gastric carcinoma cell line 23132, which had been produced under low-salt conditions (100 mmol of NaCl), antibody SC-1 reacted with a protein with a relative molecular mass of 50 kD. By altering the stringency (1 M of NaCl) and **with use of membrane preparations**, it was possible to detect other proteins with approximately 70 kD and approximately 82 kD.

Applicants submit that the whole cell extract described in Vollmers does not contain the *purified* glycoprotein encompassed by the claims because, as is evident from the specification, additional steps are required to purify the protein from a whole cell lysate. In particular, a membrane extract of the whole cell lysate is required to purify the 82 kD protein recited in the present claims.

On this point, Applicants also direct the Office's attention to the Declaration of Dr. Frank Hensel submitted with Applicants' October 30, 2007 reply. Dr. Hensel, in paragraph 3, states (emphasis added):

> Hensel et al., at page 5301, cites Vollmers et al. as describing a 50 kD protein **in whole cell lysates** bound by the SC-1 antibody. In Hensel et al., to detect the 82 kD protein, the stringency had to be altered and **membrane preparations, not whole cell lysates, had to be used**. The 82 kD protein was isolated from membrane fractions and purified by sequential size-exclusion and anion-exchange chromatography. <u>These additional steps required to purify the 82 kD protein are not described in Vollmers et al</u>.

Applicants submit that Vollmers does not describe a *purified* protein having a molecular mass of about 82 kD because Vollmers does not describe the generation of a membrane fraction of the whole cell lysate, which is a step required to purify the protein.

The Office also asserts that the specification does not "set forth a definition of the term 'purified'" and that claims are examined in a manner in which they are given the broadest

reasonable interpretation consistent with the specification. The Office states that "purified is understood in the instant case to mean the claimed purified glycoprotein is free from its original state, i.e., cell itself" and goes on to state that "[c]laim language must be analyzed, not in a vacuum, but always in light of the teachings of the disclosure as it would be interpreted by one of ordinary skill in the art." Applicants submit that the skilled artisan, in view of the specification, would not interpret the whole cell extract of Vollmers to contain the purified glycoprotein recited in the claims.

As explained above, Vollmers only describes a whole cell extract. Both Applicants' specification and Hensel teach that the 82 kD protein was not detected in a whole cell extract. It was not until the membrane fraction was separated from the whole cell extract that the 82 kD protein could be detected in the membrane fraction. Pelleting the membrane fraction from the whole cell extract and resuspending it clearly is a purification step; the membrane fraction is separated from other components in the whole cell extract. As such, Applicants submit that one skilled in the art reading the specification would understand that purification involves obtaining a membrane fraction and is not simply the glycoprotein "free from its original state, i.e., the cell itself." It is precisely when the term "purified" is read in view of the specification that the skilled artisan would understand that Vollmers does not describe the *purified* glycoprotein recited in the claims. The purification step of separating the membrane fraction from the whole cell lysate, which is described in the specification as being required to obtain the purified 82 kD protein, is not described or carried out in Vollmers.

The Office further asserts that "the discovery of a previously unappreciated property of a prior art composition ... does not render the old composition patentably new to the discoverer" and that the same reasoning holds true "when it is not a property but an ingredient, which is inherently contained in the prior art." This concern also does not apply to the present case. There is no evidence or reason to believe that the whole cell extract described by Vollmers contains the *purified* glycoprotein recited in the present claims. As explained above, an additional step, namely obtaining a membrane fraction from the whole cell lysate, is required to purify the 82 kD glycoprotein recited in the claims. This purification step is not described or carried out in Vollmers. Vollmers, accordingly, does not purify the 82 kD glycoprotein and

therefore does not teach, either expressly or inherently, every feature of the claimed invention. Applicants submit that the claims are free of the anticipation rejection over Vollmers. This basis for rejection should be withdrawn.

## CONCLUSION

Applicants submit that the application is now in condition for allowance, and such action is hereby respectfully requested.

If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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